Remarks

Claims 1, 4-6, 12 and 13 have been cancelled without prejudice or disclaimer and with the understanding that the subject matter encompassed by the cancelled claims may be pursued in a future continuation application. New claims 14-30 have been added. Support for the new claims can be found in the claims as originally filed and throughout the specification. More specifically, support for independent claims 14 and 17 can be found, for example, at page 4, lines 18-20 and in Figure 15 B and C. No new matter has been introduced by the new claims.

1. Double Patenting

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent 6,143,738 ("the '738 patent"). The Examiner asserts that the conflicting claims are not patentably distinct from each other because the '738 patent is drawn to a method for suppressing appetite or inhibiting weight gain in a mammal comprising the same compound as claimed by Applicants for treating obesity or diabetes in a mammal. According to the Examiner, it is well known that suppressing appetite or inhibiting weight gain is integral to the treatment of obese individuals who may also suffer from diabetes.

Applicants respectfully disagree with the Examiner. Claim 1 has been canceled and independent claims 14 and 17 have been added, which are directed toward methods for reducing blood cholesterol levels and blood glucose levels, respectively. Applicants submit that these claims are patentably distinct from claims 1-16 of the '738 patent directed to methods for suppressing appetite or inhibiting weight gain. Applicants therefore request that this rejection be withdrawn.

2. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 4-6 and 12-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for not reciting a recipient of the administration of the composition, *e.g.*, a mammal or human in need thereof.

Claims 1, 4-6 and 12-13 have been cancelled. New claims 14-30 indicate a recipient of the administration. Applicants therefore request that this rejection be withdrawn.

3. **Rejection under 35 U.S.C. § 102(b)**

A. The '635 Patent

Claims 1, 4 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,792,635 to Zasloff *et al.* ("the '635 patent"). The Examiner asserts that the '635 patent discloses that compound 1436 is useful in treating cardiac infarction, angina pectoris, ischemic disorders of the heart, diabetes and hypertension in a mammal. The Examiner cites the Merck Manual of Diagnosis and Therapy for disclosing that diseases such as these are known by the more generic term of atherosclerosis. Thus, according to the Examiner, the '635 patent describes the treatment of atherosclerosis by administration of compound 1436 and, as such, anticipates Applicants' claims 1, 4 and 6.

Applicants respectfully disagree with the Examiner's assessment of the subject matter described in the '635 patent and its relation to Applicants' claimed invention. Claims 1, 4 and 6 have been cancelled. New independent claims 14 and 17 are directed to methods for reducing blood cholesterol levels and blood glucose levels, respectively. The '635 patent does not describe either of these methods and is limited to the statement that "NHE-specific inhibitors would allow for the development of new therapies for a whole host of diseases or conditions." Because the '635 patent does not describe each and every feature of Applicants' claimed invention, the '635 patent cannot anticipate Applicants' claimed invention. Applicants therefore request that this rejection be withdrawn.

B. The '740 Patent

Claims 1, 4 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,842,740 to Zasloff *et al.* ("the '740 patent"). As support for his rejection over the '740 patent, the Examiner recites an identical argument to the one presented in section A above.

Applicants note that the U.S. patent cited by the Examiner is not remotely pertinent to Applicants' claimed invention and does not have Zasloff as an inventor. Applicants discovered that U.S. Patent 5,840,740 also has Zasloff as an inventor. If the Examiner intended to cite U.S. Patent 5,840,740, Applicants' comments will be based on the disclosure of this patent, which will continue to be referred to as the '740 patent. Because the Examiner's argument supporting rejection of Applicants' claims are identical to that in section A above, Applicants also rely on their arguments presented in section A for rebutting the Examiner's assertions and request that this rejection be withdrawn for at least the same reasons.

4. **Rejection under 35 U.S.C. § 103(a)**

Claims 1, 5 and 12-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '635 patent or the '740 patent in view of the Merck Manual of Diagnosis and Therapy. The Examiner asserts that the '635 and '740 patents do not expressly disclose the use of aminosterols for treating serum cholesterol or reducing blood cholesterol levels in a mammal. The Examiner further asserts that the Merck Manual of Diagnosis and Therapy teaches that elevated serum cholesterol, hypertension diabetes mellitus and obesity are the major risk factors for atherosclerosis. Thus, according to the Examiner, it would have been obvious to a person of ordinary skill in the art to employ the particular aminosterols described in the '635 and '740 patents for treating serum cholesterol or reducing blood cholesterol levels in a mammal.

Applicants respectfully disagree with the Examiner's assessment and applicability of the '635 or '740 patent disclosures, in view of the Merck Manual of Diagnosis and Therapy, to the claimed invention. Neither the '635 nor the '740 patents teach an amount of aminosterols effective to reduce either blood cholesterol levels or blood glucose levels in a mammal and the Merck Manual of Diagnosis and Therapy does not remedy this defect. It therefore would require undue experimentation by the skilled artisan to determine an effective dose to reduce blood cholesterol or blood glucose levels in a mammal. In contrast, Applicants have determined effective mammalian dosages based on experimental data such as that displayed in Figure 15 B and C. For at least this reason, Applicants request that this rejection be withdrawn.

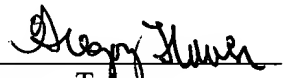
5. **Conclusion**

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, the claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,

Date: May 24, 2005



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